## **AMENDMENTS**

## In the Claims:

- 1. (Currently amended) A thermal adhesion granulation process for preparing direct tabletting formulations or aids, comprising the step of subjecting all or part of a mixture comprising:
- (a) from about 5 to about 99 % by weight of one or more diluent excipients and/or from 0 to about 99% by weight of a pharmaceutically-active ingredient;
  - (b) from about 1 to about 95 % by weight of a binder excipient; and optionally with,
  - (c) from 0 to about 10% by weight of a disintegrant excipient;

to heating at a temperature range of from about 30 to about 130°C under the condition of from about 0.1 to about 20% initial moisture content and/or from about 0.1 to about 20% initial content of a pharmaceutically-acceptable organic solvent in a closed system under with mixing by tumble rotation until the formation of granules form.

- 2. A process as defined in claim 1, wherein the temperature range is from about 40 to about 110°C.
- 3. A process as defined in claim 1, wherein the temperature range is from about 60 to about 105°C.
- 4. A process as defined in claim 1, wherein the initial moisture content is from about 2 to about 15%.
- 5. A process as defined in claim 1, wherein the initial moisture content is from about 4 to about 10%.
- 6. A process as defined in claim 1, wherein the initial organic solvent content is from about 0.1 to about 10%.

- 7. A process as defined in claim 1, where the initial organic solvent content is from about. 0.5 to about 5%.
- 8. A process as defined in claim 1, wherein the diluent excipient is powdered cellulose, microcrystalline cellulose, lactose, starch, or dibasic calcium phosphate.
- 9. A process as defined in claim 1, wherein the pharmaceutically-active ingredient is acetaminophen or ascorbic acid.
- 10. A process as defined in claim 1, wherein the binder excipient is soluble polyvinyl pyrrolidone or hydroxypropylcellulose.
- 11. A process as defined in claim 1, wherein the disintegrant excipient is crospovidone, sodium starch glycolate, reticulated carboxymethylcellulose, or low-substituted hydroxypropylcellulose.
- 12. A process as defined in claim 1, wherein the diluent excipient is microcrystalline cellulose.
- 13. (Currently amended) A process as defined in claim 12, wherein the microcrystalline cellulose is of a type in which about 90% of the microcrystalline cellulose particles are in the particle size range from about 1 μm to about 125 μm, and the average particle size of the microcrystalline cellulose particles is from about 10 μm to about 70 μm.
- 14. A process as defined in claim 1, wherein the binder excipient is soluble polyvinyl pyrrolidone.
- 15. A process as defined in claim 14, wherein the soluble polyvinyl pyrrolidone has a K value of from about 12 to about 120.
- 16. A process as defined in claim 14, wherein the soluble polyvinyl pyrrolidone has a K value of from about 20 to about 95.

- 17. A process as defined in claim 14, wherein the soluble polyvinyl pyrrolidone has a K value of from about 25 to about 35.
- 18. (Currently amended) A process as defined in claim 1, wherein the binder excipient further contains from 0 to about 10% (by weight with respect to the binder) of an anticaking agent.
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- 19. (Currently amended) A process as defined in claim 18, wherein the binder excipient contains from about 0.01 to about 10% (by weight with respect to the binder) of an anticaking agent.
- 20. (Currently amended) A process as defined in claim 18, wherein the binder excipient contains from about 2 to about 4% (by weight with respect to the binder) of an anticaking agent.
- 21. A process as defined in claim 18, wherein the anticaking agent is dibasic calcium phosphate anhydrous.
- 22. (Currently amended) A product of thermal adhesion granulation the process of claim 1 for preparing direct tabletting formulations or aids as defined in claim 1.
- (Currently amended) A powder mixture of soluble polyvinyl pyrrolidone containing from about 0.01 to about 10% (by weight with respect to the polyvinyl pyrrolidone) of dibasic calcium phosphate anhydrous.
  - $\sqrt{24}$  A direct tabletting formulation or aid comprising:
- i) from about 5 to about 99% by weight of powder cellulose, microcrystalline cellulose, lactose, starch, or dibasic calcium phosphate;
  - ii) from 0 to about 99% by weight of acetaminophen or ascorbic acid;

- iii) from about 1 to about 95% by weight of a soluble polyvinyl pyrrolidone which contains from about 0.01 to about 10% (by weight with respect to the polyvinyl pyrrolidone) of dibasic calcium phosphate anhydrous; and
- iv) from 0 to about 10% by weight of crospovidone, sodium starch glycolate, reticulated carboxymethylcellulose, or low-substituted hydroxypropylcellulose.
  - 25. (Previously added) A tablet which comprises a product as defined in claim 22.
- 26. (Previously added) A tablet which comprises the powder mixture as defined in claim 23.
- 27. (Previously added) A tablet which comprises a tabletting formulation or aid as defined in claim 24.
  - 28. (Previously added) A capsule which comprises a product as defined in claim 22.
- 29. (Previously added) A capsule which comprises a powder mixture as defined in claim 23.
- 30. (Previously added) A capsule which comprises a tabletting formulation or aid as defined in claim 24.
  - 31. (Previously added) A pellet which comprises a product as defined in claim 22.
- 32. (Previously added) A pellet which comprises a powder mixture as defined in claim 23.
- 33. (Previously added) A pellet which comprises a tabletting formulation or aid as defined in claim 24.

34. (New) A thermal adhesion granulation process, which comprises:

dry-blending binder excipient, one or more diluent excipients, and a pharmaceutically-active ingredient;

adding water and/or a pharmaceutically-acceptable organic solvent to the dry-blended mixture; and

heating at a temperature range from about 30°C to about 130°C with mixing in a closed system until granules form, wherein:

the binder excipient is from about 1% to about 95% by weight,
the one or more diluent excipients are from about 5% to about 99% by weight,
the pharmaceutically-active ingredient is from 0% to about 99% by weight, and
the water and/or the pharmaceutically-acceptable organic solvent is from about
0.1% to about 20% content before heating.

- 35. (New) The process of claim 34, wherein the mixing is by tumble rotation.
- 36. (New) A process as defined in claim 34, wherein the temperature range is from about 40 to about 110°C.
- 37. (New) A process as defined in claim 34, wherein the temperature range is from about 60 to about 105°C.
- 38. (New) A process as defined in claim 34, wherein the initial moisture content is from about 2 to about 15%.
- 39. (New) A process as defined in claim 34, wherein the initial moisture content is from about 4 to about 10%.
- 40. (New) A process as defined in claim 34, wherein the initial organic solvent content is from about 0.1 to about 10%.
- 41. (New) A process as defined in claim 34, where the initial organic solvent content is from about 0.5 to about 5%.

- 42. (New) A process as defined in claim 34, wherein the diluent excipient is powdered cellulose, microcrystalline cellulose, lactose, starch, or dibasic calcium phosphate.
- 43. (New) A process as defined in claim 34, wherein the pharmaceutically-active ingredient is acetaminophen or ascorbic acid.
- 44. (New) A process as defined in claim 34, wherein the binder excipient is soluble polyvinyl pyrrolidone or hydroxypropylcellulose.
- 45. (New) The process of claim 34, wherein a disintegrant excipient is included in the dry-blending step. (SSM, C),
- (New) A process as defined in claim 45, wherein the disintegrant excipient is crospovidone, sodium starch glycolate, reticulated carboxymethylcellulose, or low-substituted hydroxypropylcellulose.
- 47. (New) A process as defined in claim 34, wherein the diluent excipient is microcrystalline cellulose.
- 48. (New) A process as defined in claim 47, wherein about 90% of the microcrystalline cellulose particles are in the range from about 1  $\mu$ m to about 125  $\mu$ m, and the average particle size of the microcrystalline cellulose particles is from about 10  $\mu$ m to about 70  $\mu$ m.
- 49. (New) A process as defined in claim 34, wherein the binder excipient is soluble polyvinyl pyrrolidone.
- 50. (New) A process as defined in claim 49, wherein the soluble polyvinyl pyrrolidone has a K value of from about 12 to about 120.
- 51. (New) A process as defined in claim 49, wherein the soluble polyvinyl pyrrolidone has a K value of from about 20 to about 95.

- 52. (New) A process as defined in claim 49, wherein the soluble polyvinyl pyrrolidone has a K value of from about 25 to about 35.
- (New) A process as defined in claim 34, wherein the binder excipient further contains from 0 to about 10% by weight with respect to the binder of an anticaking agent.
  - 54. (New) A process as defined in claim 53, wherein the binder excipient contains from about 0.01 to about 10% by weight with respect to the binder of an anticaking agent.
  - 55. (New) A process as defined in claim 53, wherein the binder excipient contains from about 2 to about 4% by weight with respect to the binder of an anticaking agent.
    - 56. (New) A product prepared by the process of claim 34.
    - 57. (New) A tablet comprising the product of claim 56.
    - 58. (New) A capsule comprising the product of claim 56.
    - 59. (New) A pellet comprising the product of claim 56.
    - 60. (New) The process of claim 1, wherein the mixing is by tumble rotation.
- (New) A method of making a powder mixture comprising polyvinyl pyrrolidone, which comprises mixing with the composition dibasic calcium phosphate anhydrous in an amount of about 0.01% to about 10% by weight with respect to the polyvinyl pyrrolidone.

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Serial No. 09/847,017

Docket No. 205032001200